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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,607	04/08/2004	Joachim Ernst Kramer	P06300US02-PHI 1483	9485

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,607	KRAMER, JOACHIM ERNST	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 20 April 2005.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 04/20/05 in reply to the Office action of 11/19/04 has been entered. Claim 2 is amended. Claims 11 and 12 are added. Therefore, claims 1-12 are pending and are examined.

All previous objections and rejections not set forth below have been withdrawn.

New Matter

The amendment filed 04/20/05 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the material inserted into the original specification at page 76, the last sentence of 1st paragraph, stating, "Unauthorized seed multiplication prohibited. U.S. Protected Variety ". Nowhere in the originally filed disclosure provide basis for such introduced material.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, 2nd

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 12 are omnibus type claim because it refers to a Table. The claims recite "the SSR loci listed in Table 4". MPEP states as follows: "Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). See MPEP § 608.01(m).

Written Description

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 11/19/04. Applicant's arguments filed 04/20/05 have been considered but are not deemed persuasive.

Applicant argues that the specification provides sufficient written description of the claimed invention by actual reduction to practice of F1 hybrid seed/plants produced from inbred maize line PH94T and by description of common identifying characteristics structural feature which is the deposited seed of inbred PH94T, as well as by description of SSR marker profiles as shown in Table 4 of the specification. Applicant

cites Enzo Biochem. Inc., 323 F3d at 965, 63 U.S.P.Q. 2d at 1613 to support the deposit section of the arguments (response, p. 7).

These are not persuasive because the specification does not provide a representative number of seed/plant hybrids of the genus claimed. The performance comparisons of three hybrids (Tables 3A-3C) produced by crossing maize line PH94T with three/four other plants cannot be extended to any other hybrid plant that does not have both of the same parents, and are not representative of *all* hybrids produced using maize line PH94T as only one parent and using a multitude of genetically and morphologically uncharacterized and unrelated corn plants as a second parent.

Regarding the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposit material, it is noted that in the patent considered in that decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case for the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed. As in *Enzo*, here the deposited inbred seed does not correspond exactly to the claimed F1 hybrid. However, the functions of the claimed hybrid plants have not been correlated to the set of chromosomes originating from the deposited PH95T seed. The function of the plant grown from a PH94T seed is correlated with the structure of its entire genome. The functions of the claimed hybrid plants grown from the claimed hybrid seeds are correlated with the structures of their entire genomes, not just the set of chromosomes inherited from PH94T. Further, half of the alleles of the hybrid are inherited from the

other parent, and are not described by the deposited PH94T seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited Ph94T seed. The deposited seed provides written description only for the F0 seed/plant of inbred PH94T, and the methods that employ said F0 plant/seed. The deposited material does not provide written description for F1 hybrids produced from inbred PH94T.

Applicant asserts that the claimed hybrids are in accordance with Eli Lilly standard based on the assertion that cells and/or chromosomes of inbred line PH94T provide structural characteristics sufficient to distinguish them from hybrids that do not made with PH94T. Applicant also relies upon deposited seed of inbred line PH94T and the SSR profiles of Table 4 to support his position (response, page 7, 2nd full paragraph; and page 8, 1st full paragraph).

Examiner maintains that the deposited seed of the inbred line PH94T does not provide written description for F1 hybrids produced from the line PH94T as discussed above. While the claimed hybrids will inherit the SSR marker profile of PH94T, they will not inherit the same genetic markers from the other parents (non-PH94T parents involved in the breeding) because they have different parents having different markers. The SSR marker profiles of other parents are not described. In addition, the specification does not describe the traits that are associated with the SSR loci of Table 4. While SSR are named, the written descriptions of the sequence of each of the SSR markers are not provided. Without a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant.

Applicant continues, citing the decision of *The Regents of the University of California v. Eli Lilly and Co,* and Applicant argues that in this application, all of the members of the claimed genus of hybrids having PH94T as one parent share the identical feature of having the genomic characteristics of the inbred PH94T.

This is not persuasive for the reasons explained above. The hybrids do not have the entire genomic characteristics of PH94T, but only one set of chromosomes. In *Eli Lilly*, the members of the genus shared a common function. In the instant application, the specification does not describe the functions (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the functions of the hybrids with the structure of the genetic complement or the set of chromosomes from PH94T.

Applicant correctly states that it is well known that a hybrid made from an inbred will receive one set of chromosomes from that inbred. However, Applicant incorrectly asserts that a genus of F1 hybrid seed and plants encompassed by claims 1-10 all share the common structural attribute of having a complete set of the unique chromosomes of PH94T. Which implies that each F1 hybrid produced from PH94T will comprise this unique set of chromosome of PH94T. Applicant further asserts that this unique of chromosomes described in the SSR profile of Table 4 of the specification is sufficient to describe the genus of claimed hybrids (response, paragraph bridging pages 8 and 9).

Examiner agrees with Applicant that a hybrid produced from inbred will receive one set of chromosomes from that inbred, regardless of whether the inbred is used as male or female parent of the F1 hybrid. However, where the breeding involves unknown

various non-PH95 parents, all F1 hybrids will not receive the same set of chromosomes from each of the parents involved in the breeding. For example, if PH94T carries two recessive alleles for insect resistance, it will be susceptible to insects. If it is crossed to another inbred with a recessive allele at that locus, the hybrid will also be susceptible to insects. If the other chosen inbred has a dominant allele at that locus, the hybrid will be insect resistant, if simple Mendelian genetics governs the inheritance of this trait. Each inbred possesses thousands of genetic loci governing thousands of traits, including silk color, lodging resistance, leaf color, stalk color, disease resistance, stalk stiffness, waxy starch, days to maturity, etc., with a dominant or recessive allele at each locus. It is the interaction between the two sets of alleles from both parents that determine the morphological and genetic characteristics of the F1 hybrid, rather than a set of alleles from inbred PH94T. One cannot predict which set of alleles a hybrid will receive from its parent. Applicant has provided no scientific evidence to support the conclusion that the genetic/morphological characteristics of all F1 hybrid seed/plants, produced from crossing inbred PH94T with any other maize line, are not expected to vary from inbred PH94T. Applicant has provided no evidence that these F1 hybrids are reproducible.

Applicant alleges that the Examiner is setting a standard of written description that exceeds that required by law. However, Applicant points to no specific requirement set forth in the last Office action that exceeds the written description requirement as set forth in the MPEP 2163 or related case law.

On the paragraph bridging pages 10 and 11, Applicant repeats his argument that the deposit of the seed of inbred PH94T is sufficient to describe F1 hybrid plants/seed and that the unique set of chromosomes from inbred PH94T distinguishes them from non-PH94T hybrids. Applicant continues to cite Enzo. Biochem and Eli Lilly.

However, again, hybrids that do not share both of the same parents will not have the same traits and the fact that they share one set of chromosomes from PH94T does not provide any description for the hybrids. The claimed hybrids will not have the similar morphological and physiological characteristics as PH94T. PH94T plants can be crossed with any other inbred maize plant to produce the claimed hybrids. The claimed hybrids then will express a combination of set of alleles that are different from each other, and which are also different from those expressed by PH94T. That all hybrids will inherit two sets of alleles from PH94T does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids.

At page 12 (the 2nd full paragraph), Applicant asserts that Examiner does not relate how the rejection applies to claims 7-10. Applicant asserts that pericarp tissues from the inbred will be a component of the F1 hybrid seed, when PH94T is the maternal parent. Therefore, Applicant continues to assert, such genetic composition of the pericarp tissue of the F1 seed is an identifying structural characterizes for F1 seed and plants produced from said seed. Applicant admits, however, that maize seed is

comprised of various types of tissues with different genetic compositions, rather than only pericarp tissues.

Examiner responds that the rejection applies to claim 7-10 the same way as it applies to claims 1-6. Claims 7 and 9 encompass F1 hybrid seed, while claims 8 and 10 encompass F1 hybrid plants or part thereof produced from the F1 hybrid seed. Firstly, the rejected claims are not drawn to pericarp tissues from the deposited maize seed but rather F1 hybrid seed and plants of PH94T. Secondly, even if one assumes that F1 hybrid seed receive an intact cell from a maternal inbred parent PH94T, the morphological characteristics of the F1 seed is not determined by the genetic material of the intact cell only. Thirdly, since maize seed is made up of various types of tissues with different compositions, it is the interaction between the genetic materials of these various tissues that determines the morphological characteristics of the seed. In addition, the rejected claims do not recite inbred PH94T is used as the maternal parent for all hybrids.

On page 14 of the response, Applicant summarizes his arguments as follows: a) the cells/chromosomes of inbred of PH94T provide identifying structural feature common to all members of the genus of F1 hybrids; b) each hybrid of PH94T receives a complete set of chromosomes of PH94T, and a description of the set of chromosomes is disclosed in Table 4 of the specification; c) SSR profile of PH94T is obtainable from the deposited seed of PH94T and that methods of using SSR markers are known in the art; d) F1 hybrid seed and plants produced from said seed will contain an intact cell from

inbred PH94T. Applicant asserts that these descriptions are sufficient to provide distinguishing characteristics for the F1 hybrid plants/seed.

However, examiner maintains that hybrids that do not share both of the same parents will not have the same traits and the fact that they share one set of chromosomes from PH94T does not provide any information concerning the morphological and physiological characteristics that will be expressed by the hybrids. The morphological/genetic characteristics of the hybrids are not determined by one set of chromosomes from parent PH94T, but rather the interaction between the genetic materials from both parents. Regarding the SSR markers, the specification does not describe the traits that are associated with the SSR loci of Table 4 and the written descriptions of the sequence of each of the SSR marker are not provided. Without a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant. In addition, the specification does not describe the SSR marker profiles of other non-PH94T parents involved in the breeding.

Therefore, for all the reasons discussed above and in the last Office action, the claimed invention lacks adequate written description. The rejection is maintained.

Remarks

The claims are deemed free of the prior art, given that the prior art does not teach or fairly suggest a hybrid maize seed/plant produced from the inbred maize PH94T, as stated in the last Office action.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/10/05
Mai

Medina A. Ibrahim

MEDINA A. IBRAHIM
PATENT EXAMINER